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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,243	10/15/2001	Juan-Carlos Diaz	P842 CIP	4113

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EXAMINER	
THALER, MICHAEL H	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/978,243	DIAZ, JUAN-CARLOS
	Examiner	Art Unit
	Michael Thaler	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2,3*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Upon reconsideration, the election of species requirement is withdrawn.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 7, the meaning of "stent cup plunger" is unclear since a "cup", by definition, has sides to hold something while the "cup" plunger 66 as described on page 7, lines 10-15 of the specification and shown in figures 3 and 4 appears to be a planar ring without sides. Other claims have this problem. In claim 1, line 26, after "of", "a" should be "said" since the fluid receiving chamber has already been claimed in line 11. Claim 11 has the same problem. In claim 6, line 2, "is a is a" is not understood. Claim 16 has the same problem. In claim 7, line 2, "wherein and inside diameter" is not understood. Claims 9, 17 and 19 each have the same problem. In claim 24, there is no antecedent basis for "said stent graft assembly". In claim 25, lines 6-7, it is not seen how a stent can be disposed around the stent. In claim 27, line 3, "material" should be "materials".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7/1, 8/7/1, 9/1, 10/9/1, 11, 17/11, 18/17/11, 19/11, 20/19/11, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler (5,817,101) in view of Bartholf et al. (2001/0034549). Fiedler, in figures 1-3, discloses catheter 22 having a guidewire lumen 24 and pressurizing lumen 26, fixed seal mount (the portion of catheter 22 which supports seal 38), sheath 36 having a movable seal mount (the portion of sheath 36 which supports seal 40), wherein a stent retention portion of said sheath (the portion of sheath 36 which surrounds stent 50 prior to stent deployment) is made of a first material having a lubricious inner surface (col. 7, lines 1-8), wherein a stent retraction portion of said sheath (the proximal portion of sheath 36 which surrounds seal 38 prior to stent deployment) is made of a second material (which is the same material as the first material) having a smooth inner surface, first seal structure 38 and second seal structure 40. Fiedler fails to disclose a "stent cup plunger" to provide a backing for the stent. However, Bartholf et al. teach that a stent should be supported or backed by a rigid stop 22 to

prevent it from migrating proximally within the sheath during sheath retraction (paragraph [0028]). It would have been obvious to include a rigid stop on the Fiedler catheter 22, separate from flexible seal 38, so that it too would have this advantage. As to claims 8, 10, 18 and 20, Fiedler fails to disclose a backstop to limit the retraction of the sleeve. However, it is old and well known in this art to use a backstop on a stent deployment catheter in order to insure that the sleeve does not retract too far. It would have been obvious to include a backstop on the Fiedler catheter 22 so that it too would have this advantage. As to claims 9, and 19, Fiedler fails to disclose the distal portion of sheath (opposite the stent retention section of catheter 22) as having an inside diameter which is different than the inside diameter of the proximal portion of the sheath (opposite the stent retraction section of catheter 22). However, Bartholf et al. teach that the diameter of the distal portion 44 of a stent deployment sheath should be larger than the diameter of its proximal portion in order to minimize the diameter of the proximal portion to provide a large clearance between it and a guiding catheter (paragraph [0032]). It would have been obvious to provide different diameters on the proximal and distal portions of the Fiedler sheath 36 so that it too would have this

advantage. As to claim 23, Fiedler fails to disclose the distal portion of sheath as having a wall thickness which is different than the wall thickness of the proximal portion of the sheath. However, it is old and well known in this art to make the distal portion of a stent deployment sheath of a thickness which is smaller than the thickness of its proximal portion in order to facilitate its insertion and advancement through the vasculature. It would have been obvious to make the wall of the distal portion of sheath 36 thinner so that it too would have this advantage.

Claims 2-6, 7/(2-6), 8/7/(2-6), 9/(2-6), 10/9/(2-6), 12-16, 17/(12-16), 18/17/(12-16), 19/(12-16) and 20/19/(12-16) would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 21, 22 and 25-27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
2/2/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731